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**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS
LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

ALL CASES

MDL No. 2419
Docket No. 1:13-md-2419 (RWZ)

**PREMIER ORTHOPAEDIC ASSOCIATES, ET AL'S OPPOSITION TO THE
VANDERBILT UNIVERSITY'S MOTION TO QUASH SUBPOENA FOR DEPOSITION
BY WRITTEN QUESTION**

Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Rhaul Shah, M.D., John Catalano, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. (collectively, "Premier Defendants" or "Premier") hereby oppose The Vanderbilt

University's ("Vanderbilt") Motion to Quash the Subpoena for Deposition by Written Question (Docket Number ("Dkt. No.") 2781, 2782, 2783, 2784).

BACKGROUND

The New England Compounding Center ("NECC") had thousands of customers across the nation prior to the 2012 fungal meningitis outbreak culminating in this litigation. According to the "(NECC) Customer List since 5/21/2012," an entity which NECC classified as "VMG Clinic Pharmacy" located at "1211 Medical Center Dr. TVC 1815, Nashville, TN 37232" placed a single order with NECC for 350 units of "Povidone Iodine 5% drops 1 mL" on September 25, 2012. (<http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf>, pg. 331 of 345). The Vanderbilt University Medical Center is located at 1211 Medical Center Drive, Nashville TN and responded to the Premier Defendants' subpoena for deposition by written question. (<https://www.mc.vanderbilt.edu/>; Dkt. No. 2782.)

The current motion at bar is a Motion to Quash by Vanderbilt, asking the Court for protection from responding to Premier's Notice of Deposition by Written Question. Vanderbilt's basis for this request is essentially that (1) the information sought by Premier is irrelevant; and (2) the discovery sought is disproportionate to the needs of the MDL.

Per the agreed-upon discovery schedule submitted by the Premier Defendants to this Court on March 31, 2016, Common-Issue Fact Discovery is currently ongoing until June 1, 2016 with a proposed new deadline of August 1, 2016. (Dkt. No. 2775.)

SUMMARY OF ARGUMENT

The Premier Defendants have sufficient factual basis to demonstrate the relevance of the information sought by subpoenaing Vanderbilt for a deposition by written question. The potential allegations available to the PSC and the record thus far, including facts, emails, and deposition

testimony, demonstrates the relevance of information regarding large entities' due diligence when making the decision to purchase from NECC. The Premier Defendants' direct examination questions and choice of deposition by written question format were selected to make the burden on non-parties minimal such that the discovery sought was proportionate to the needs of the MDL.

ARGUMENT

Discovery is wide-ranging in scope, extending to "any non-privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case," regardless of whether the information is admissible in evidence. Fed. R. Civ. Pro. 26(b)(1).

"A Rule 45 subpoena must fall within the scope of proper discovery under [Rule] 26(b)(1)." *Enargy Power (Shenzhen) Co. Ltd. v. Xialong Wang*, No. 13-11348-DJC, 2014 WL 2048416 at *2 (D. Mass. May 16, 2014). Therefore, following the 2015 Amendments to Rule 26, "information sought must be: (1) not privileged; [and] (2) relevant to the claim or defense of any party." *Id.* Additionally, a court is only required to quash a subpoena if the subpoena, among other unrelated factors, "subjects a[n entity] to undue burden." Fed. R. Civ. Pro. 45(d)(3)(A)(iv).

I. The Premier Defendants Seek Relevant Information Regarding Vanderbilt's Due Diligence in Deciding to Purchase from NECC

The 1st Circuit requires the party issuing the subpoena to demonstrate sufficient "factual support" for its contention that the information sought is relevant to that party's defenses. *Enargy*, 2014 WL 2048416 at *3. Where the party issuing the subpoena speculates as to the "possibility" of relevance without factual support, concedes that it does not need the information, or makes overbroad requests for information, the Court has quashed subpoenas or limited their scope. However, none of those situations apply to the Premier Defendants, who have argued the necessity for this information from the outset, kept their requests for information as targeted and minimal as

possible, and will herein provide factual support based on the current record as to the relevance of the information sought. Accordingly, Premier's subpoena issued to TEC should be upheld.

The Premier Defendants argued before this Court as to "what other clinics who purchased from NECC did" prior to deciding to purchase from NECC. (Transcript of December 17, 2015 Oral Argument before Judge Boal, pg. 14 ln. 3-4.) That due diligence was and remains the focus of the Premier Defendants' questions and intent in subpoenaing Vanderbilt for a deposition by written question.

a. The Premier Defendants Selected Vanderbilt Due To Geographic Location and Size

As discussed in the Premier Defendants' Opposition to The Emory Clinic's ("TEC") Motion to Quash Subpoena for Deposition by Written Question, multiple factors played into the Premier Defendants' decision of clinics to subpoena for deposition by written question. These included geographic location, entity size, number of orders, quantity of medication purchased, and type of medication purchased.

Vanderbilt is a large entity which purchased from NECC. In fact, Vanderbilt is one of the few such large entities within Tennessee which purchased from NECC but is not a party to this litigation; the other entity which fits that criteria is the Saint Thomas Outpatient Neurosurgical Center ("STOPNC"), a defendant in this litigation and also located in Nashville.

As discussed in Premier's Opposition to TEC's Motion to Quash, the Premier Defendants posit that large entities which decided to purchase from NECC likely had more financial resources and personnel to devote to investigation of NECC as part of their due diligence in using NECC as a vendor. Such large entities also likely place value on their reputation and name in the field, and accordingly would hold themselves to a higher standard as well as receiving more attention regarding their compliance with internal due diligence policies and procedures. While the Premier

Defendants maintain that the investigative efforts the PSC contends were required were in fact above and beyond the standard of care, evidence from large institutions can support that defense. The Premier Defendants anticipate that even large entities without financial and personnel constraints did not submit FOIA requests, do extensive investigations, or conduct in-person inspection of NECC. The testimony of Ms. Kimberly C. Mason, 30(b)(6) witness for the University of Tennessee Medical Center, has borne out these anticipations.

b. The PSC's Potential Allegations Regarding the Premier Defendants' Due Diligence Form the Basis for The Subpoena

“Discovery procedures set forth in the Federal Rules of Civil Procedure seek to further the interests of justice by minimizing surprise at trial and ensuring wide-ranging discovery of information.” *Enargy*, 2014 WL 2048416 at *2 (citing *Cartel Asset Mgmt. v. Ocwen Fin Corp.*, No. 01-cv-01644, 2010 WL 502721, *9 (D. Colo. Feb.8, 2010)).

The Premier Defendants seek information “relevant to [their] . . . defenses,” regardless of the core product at issue in this MDL. Those defenses must be constructed to answer allegations regarding the Premier Defendants’ due diligence when deciding to purchase from NECC. Correspondingly, the information sought via the deposition by written question’s direct examination is aimed at *the due diligence conducted as part of the decision to purchase from NECC*. While the choice of product purchased by customers from NECC is relevant (in that those who did not unknowingly purchase tainted MPA are not involved in this litigation), it cannot at this time comprise the sole determinative factor as to whether information on the due diligence behind an entity’s decision to purchase from NECC is relevant to the Premier Defendants’ defenses in this case.

Additionally, the Premier Defendants do not know what exact allegations the PSC will present at trial. Plaintiff’s expert Dr. Winikur recently testified in oral deposition that no one should

have purchased from NECC at all, and the only investigation required to reach that conclusion was internet research. Accordingly, it is possible that the Premier Defendants will face allegations that they should not have ordered from NECC at all – regardless of what product they ordered. In such instance the Premier Defendants have the right to be armed with all the discovery information possible in order to minimize surprise at trial.

Finally, we do not know that Vanderbilt or any institution subject to these depositions by written questions did not do an investigation into NECC's facility (i.e. inspection, internet research, etc...) without first having the deposition questions answered. It may be the case that Vanderbilt investigated NECC during the relevant time period and found the facility to be reputable and suitable for their purposes of ordering compounded medications. Such evidence would be extremely relevant to prove just exactly what would have been found if Premier performed the same investigation at that same time – in other words the information is potentially relevant to causation, not only standard of care.

c. NECC's Marketing Strategy Focused on Persuading Customers to Outsource Entirely to NECC Following Initial Sale

As explained at some length in the Premier Defendants' Opposition to TEC's motion to Quash, NECC's marketing appears in large part to be based on getting a foot in the door with customers and then expanding to become customers' "one-stop shopping" for compounded medication. (NECC_MDL000097060, Track "15.) Baclofen.") There is some indication in the NECC production thus far that customers would purchase certain product(s) from NECC and later on inquire about other products. In this way NECC would expand its business and customers would continue to be able to serve patients.

The Premier Defendants assert that it is unlikely NECC's customers would repeatedly investigate NECC as to the different products available after conducting their initial due diligence.

It does not appear from the evidence available thus far that different due diligence was conducted for different products. Accordingly, whatever due diligence an entity conducted on NECC was likely to be its only investigation into NECC's suitability as a vendor, and would not likely change once the customer decided to buy different product.

II. The Premier Defendants' Subpoena for Deposition by Written Question is Proportionate to the Needs of the MDL

Whether discovery sought is "proportional to the needs of the case" includes consideration of "importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. Pro. 26(b)(1). But discovery remains broad in scope, encompassing "any non-privileged matter that is relevant to any party's claim or defense," regardless of whether the information is admissible in evidence. Fed. R. Civ. Pro. 26(b)(1).

The Premier Defendants do not answer for the cross-examination questions posed by the PSC and lodged multiple objections to form with the Court within the appropriate time period regarding the PSC's cross-examination. (Dkt. No. 2640.)

a. Due Diligence is the Heart of Potential Allegations Faced by the Premier Defendants

The information sought by the Premier Defendants is directly relevant to stated and potential allegations from the PSC as to the Premier Defendants' due diligence in deciding to purchase from NECC. The due diligence and (on the converse side of due diligence) the marketing practices, of various other non-party entities such as Clint Pharmaceuticals and Anazeo have been

probed at length by various counsel in the depositions of witnesses with connections to said entities.

As previously argued at length, the Premier Defendants' direct examination questions are narrowly targeted to the due diligence conducted by Vanderbilt in deciding to purchase from NECC.

b. The Potential Amount in Controversy Favors Allowing the Premier Defendants' Requested Discovery

Currently, the Premier Defendants face suits from over fifty plaintiffs in the state of New Jersey. Unknown millions have likely been paid by Settling Defendants; the Bankruptcy Trust is charged with disbursing millions of dollars more to plaintiffs. Yet given the volume of the plaintiffs and extensive nature of some of the injuries alleged, the Premier Defendants anticipate that Plaintiffs will seek a verdict or settlement easily into the tens of millions of dollars. Given the potentially massive amount in controversy, the Premier Defendants require sufficient discovery to support defenses which may have to stand in the face of incredibly expensive claims.

c. The Premier Defendants Have No Other Means of Acquiring the Discovery Sought

The Premier Defendants have no means of learning about Vanderbilt's due diligence in deciding to purchase from NECC other than by deposition. Explanation of Vanderbilt's, or any other non-party's, investigation into NECC is not publicly available or easily discoverable by any other means than direct inquiry, for which a subpoena and notice of deposition are generally required when seeking response from a non-party to litigation.

d. Deposition by Written Question of Multiple Entities is the Most Efficient Means of Obtaining Information while Conserving All Parties' Resources

The Premier Defendants are a small ambulatory surgery center and collection of individual physicians facing a large multi-district litigation with only the protection provided by their malpractice insurance. Counsel for the Premier Defendants are a small firm with limited financial and personnel resources and multiple other caseloads to manage. In all efforts, counsel's goal is to provide the zealous representation at reasonable cost to the client. Accordingly, counsel for the Premier Defendants have attempted to pursue all discovery options available for their clients' protection, cognizant of the financial and time constraints which exist. Furthermore, in arguing previously before the Court for the deposition by written question to remain in that format rather than be conducted orally, the Premier Defendants were motivated in part by keeping the burden on the non-parties subpoenas minimal, as several of which are small clinics similarly situated to the Premier Defendants in terms of limited resources available to engage in litigation in which they were not party.

e. The Premier Defendants Intend To Offer Evidence of the Standard of Care With Information Gained Via Depositions by Written Question

Whether other institutions actually performed the investigations the PSC contends were required is information which can be used in support of expert testimony at trial. The Premier Defendants are cognizant of the applicable New Jersey law and do not suggest that such information would be used in place of expert testimony to establish the standard of care.

However, information obtained from Vanderbilt can be used to bolster expert testimony and is potentially useful in that context. Obtaining information from entities both analogous to and surpassing the Premier Defendants in size and resources is useful to support the Premier Defendants' position that in 2012, the standard of care did not require the extensive checks the PSC contends were required. While the practices of other healthcare providers may be deemed inadmissible to prove the standard of care, this situation is distinguishable. In the current case,

Vanderbilt and the other non-party entities ordered directly from NECC just as Premier and the other defendants ordered from NECC. In that instance, there is a nexus that joins the non-parties to events in this case making their conduct relevant.

Vanderbilt's contention that the information sought could not be used to establish standard of care does not mean the information sought could not be used at all; nor does the admissibility in evidence of the information sought preclude the Premier Defendants from asking questions in the discovery stage.

f. The Premier Defendants' Need for Cumulative Information on Due Diligence Outweighs the Minimal Burden Imposed by the Subpoena

In conducting a deposition by written question and proffering twenty-one questions specifically aimed at certain types of due diligence, the Premier Defendants have taken pains to make the burden on non-parties as minimal as possible in efforts to keep their use of discovery tools in proportion to the needs of the case. It is difficult to imagine how the Premier Defendants' questions could have been more limited while still conforming with litigation practice rules and ascertaining the information necessary. Furthermore, no reasonable reading of Rule 30(b)(6) requires the extensive effort Vanderbilt claims is required in order to respond to the questions posed.

Thus far, the burden of these depositions has been minimal on responding entities. These entities have been able to produce an individual with knowledge or educated to have the knowledge sought with little issues, schedule the deposition entirely at the convenience of the witness and witnesses' counsel with no other conflicting scheduling considerations, and the depositions themselves have taken around two hours or less – with only a minor portion of that time taken up by responding to the Premier Defendants' direct examination questions.

CONCLUSION

For the reasons stated herein, the Premier Defendants respectfully request that the Court DENY The Vanderbilt University's Motion to Quash the Premier Defendants' Subpoena for Deposition by Written Question.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATION

I certify that in submitting this *OPPOSITION*, I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's System, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: April 21, 2016

/s/ Christopher M. Wolk
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